

REMARKS

Claims 1-20 are pending. Claims 1-20 are rejected. Claims 1-20 have been canceled. New claims 21-65 are added. No new matter has been added, and the new claims are fully supported by the Specification.

The Office Action objects to the disclosure because it is asserting that page 3 of the present specification has a hole at the top. Applicants have attached hereto a copy of page 3 of the specification for the Examiner's convenience. No new matter has been added.

Additionally, Applicants take this opportunity to correct the specification. Applicants submit that the Specification includes a typographical error at page 8, line 22. Accordingly, Applicants respectfully amend the Specification at page 8, line 22 to recite 1.5-3.5 : 0.03-0.35 :0-1. This amendment is fully supported by original claim 16, which correctly recites the value 0.35.

The Office Action objects to the asserted absence of an abstract under 37 CFR § 1.72(b). Applicants have attached hereto a substitute Abstract.

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of co-pending Application No. 09/926,396. Although the conflicting claims are admittedly *not identical*, the Examiner contends that these claims are not patentably distinct from each other because they are both drawn to methods of isolating sterols from neutral substances obtained from soap.

Applicants note the obviousness-type double patenting rejection, and to the extent that the rejection may apply to the new claims, Applicants respectfully request an abeyance while other issues regarding the present application remain outstanding. Applicants will address the materiality of the double patenting rejection at the time the application is otherwise allowable.

Original claim 6 is objected to under 37 CFR 1.75(c) as having an improper dependent form for failing to further limit the subject matter of a previous claim. Original claim 6 recites "a weight ratio of 1: 1-3: 2-6," which the Office Action asserts is broader than the weight ratio of 1: >1: >1 as recited in original claim 5. Per the Office's request, Applicants respectfully submit claim 27. Additionally, Applicants have corrected the typographical error noted by the Examiner in claim 25 (formerly claim 4) to recite 140°C.

Claims 1-20 are rejected under 35 USC 103(a) as being unpatentable over US Patent No 2,530,810 to Christenson et al ("Christenson") and US Patent No. 4,153,622 to Lamminkari et al ("Lamminkari") in combination. This rejection is traversed as it may apply to the new claims.

The Office Action asserts that the references teach isolating sterols from neutral substances by evaporation fractionating/distillation of a hydrocarbon fraction containing said neutral substances in order to obtain a sterol-rich fraction, re-dissolving said sterol-rich fraction in a solvent, crystallizing from said solvent and separating the sterol crystals obtained from said solvent. The Office Action asserts that the combined teachings of the above-cited references would have been obvious to the skilled artisan in the art at the time of the present invention.

Christenson discloses a method of separation of unsaponifiable matter from tall oil residue. According to Christenson, a solution of unsaponifiable matter in aqueous alcohol is extracted using a solvent such as naphtha, chlorinated hydrocarbons, ethers and the like, to obtain a fraction highly enriched in unsaponifiable matter. The extract solution is washed with water to remove the residual soaps. Subsequently, the solvent from the extract solution is evaporated before refining the sterols by crystallization. Finally, the sterols are separated from the crystallization solvent, which may be methanol or another lower alcohol, acetone, or another solvent of sterols. See Christenson, column 2, lines 33-48, column 6, lines 50-55 and 70-76, and column 7, lines 1-54.

Lamminkari discloses a process for the recovery of β -sitosterol from a mixture of sterols in unsaponifiables obtained from crude soap skimmings. The unsaponifiables and activated carbon are suspended in acetone. The mixture is distilled until the acetone is boiled off. The residue from the distillation is redissolved in a mixture of acetone and alcohol, preferably ethanol. The acetone-alcohol solution is cooled to cause precipitation. The precipitate is filtered and dried to promote recovery of the sterols. See Lamminkari, column 2, lines 55-68 to column 3, lines 1-10.

New claim 21 claims a method for separating sterols from neutral substances. A hydrocarbon fraction containing neutral substances must be provided. The hydrocarbon fraction is optionally washed with water. The neutral substances are separated from the hydrocarbon. Subsequently, the neutral substances from the previous step are subjected to evaporation fractionating to obtain a sterol-rich fraction. The sterol-rich fraction is dissolved in a water-containing solvent mixture. The sterols are crystallized

and separated from the solvent.

As discussed in more detail below, Applicants submit that the obviousness rejection is overcome for at least the following reasons: 1) neither of the references teach or suggest step (d) in claim 21; and 2) neither of the references teach or suggest a crystallization as required in step (e). Additionally, Applicants note that neither of the references includes an optional washing step as recited in claim 21.

First, Applicants note that step (d) of claim 21, which involves evaporation fractionation of neutral substances, is not taught or suggested by the references. The references only teach or suggest that the solvent is removed by distillation.

Second, neither of the references discloses a crystallization step in which the sterol-rich fraction is dissolved in a water-containing solvent mixture, as claimed in claim 21 of the present invention. In Christenson, Example X (Christenson, column 7, lines 36-45) only dictates treating unsaponifiable matter with methanol, acetone, or other solvent of sterols. In Lamminkari, the residue is dissolved in a mixture of acetone and alcohol. See Lamminkari, column 2, lines 55-68 to column 3, lines 1-10. Thus, neither Christenson nor Lamminkari disclose the chemical properties of the solvent in the crystallization step as disclosed by the present invention.

Third, claim 21 of the present invention claims an *optional* step involving washing with water. In contrast, the washing step disclosed in Christenson appears to be a *required*, i.e. non-optional, step. Although Christenson suggests that the amount of washing may be increased and decreased according to external factors, it does not indicate that the washing step may be completely eliminated. See Christenson, column 6, 51-54 and column 7, lines 9-14. Furthermore, Lamminkari does not disclose an

optional washing step with water. Rather, this reference discloses non-water washing steps, which appear optional. See Lamminkari, column 4, 45-60 and 55-58.

Again, the references do not contain each and every step of the claimed invention, and therefore claim 21 of the present invention would not have been rendered obvious.

Applicants submit that claims 22-44 depend on claim 21, and therefore claims 22-44 should also be allowed for at least the same reasons.

For at least the above reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 21-65, and the prompt issuance of a Notice of Allowability are respectfully solicited.


Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper,

may be charged to counsel's Deposit Account No. 01-2300, **referencing docket number 023406-00008.**

Respectfully submitted,

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RJB:RJC/RN/ksm

Enclosures: Substitute Abstract
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Petition for Extension of Time (3 months)